## Campaigners for healthcare & justice Rose Irwin & Brenda Livsey (Rosalind Urion)

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Dockets management Branch FDA Department of Health & Human Services Rm 1061 5630 Fishers Lane Rockville MD 20852 USA

20 December 2003

Dear Sirs,

## FDA DECISION ON SILICONE-GEL BREAST IMPLANTS

I write to you as a casualty of silicone gel implantation and as a campaigner who has had the experience of hearing many, many accounts of the adverse effects from these devices. A help line set up in 1996 by a casualty here in the UK received 3,500 calls on this within several months of being set up.

We have a list of UK doctors who have expressed grave misgivings about the risk over benefit ratio. These are doctors who have encountered patients with disease symptoms that give evidence of being linked to the implants, particularly elderly or leaking implants. Unfortunately, only a few of these doctors are willing to raise their heads above the parapets and speak out on this topic; though several have courageously continued to express their opinions in the media.

My plea is that you might find means to further delay the decision by the FDA to lift the moratorium on silicone breast implants - a decision based, I gather, on a very narrow majority vote by your committee.

Yours sincerely,

2003P-053D

Rosalind Urion, Action Against Silicone-Gel, UK

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